Supreme Court, U.S.
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(1)

No. 95-886

In the

Supreme Court of the United States

October Term, 1995

LORA LOHR AND MICHAEL LOHR,
Cross-Petitioners,

v.

MEDTRONIC, INC.
Cross-Respondent.

On Cross-Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

ROBERT L. COWLES
DANIEL C. SHAUGNESSY
COWLES & SHAUGNESSY, P.A.
Suite 901
233 East Bay Street
Jacksonville, FL 32202
(904) 359-9500

BRIAN WOLFMAN
(Counsel of Record)
ALLISON M. ZIEVE
ALAN B. MORRISON
PUBLIC CITIZEN LITIGATION GROUP
1600 20th Street, N.W.
Washington, D.C. 20036
(202) 588-1000

ROBERT F. SPOHRER
SPOHRER, WILNER & MAXWELL, P.A.
444 East Duval Street
Jacksonville, FL 32202
(904) 354-8310

Attorneys for Cross-Petitioners

December 6, 1995

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QUESTION PRESENTED

Do the Medical Device Amendments to the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360c *et seq.*, preempt state-law tort claims to recover for injuries caused by a defective medical device?

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for the Eleventh Circuit

CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

Cross-petitioners Lora Lohr and Michael Lohr hereby petition for review of a ruling of the United States Court of Appeals for the Eleventh Circuit concerning injuries suffered by Ms. Lohr at the hands of cross-respondent Medtronic, Inc.'s allegedly defective cardiac pacemaker lead. Specifically, the court of appeals held that cross-petitioners' state-law claims based on an alleged breach of the common-law duty-to-warn and defects in the manufacturing of Medtronic's lead were preempted by the Medical Device Amendments to the federal Food, Drug and Cosmetic Act.

The Eleventh Circuit also held that cross-petitioners' claims based on the defective design of the medical device were *not* preempted, which form the basis of Medtronic's petition for writ of certiorari filed on November 13, 1995.

Medtronic, Inc. v. Lohr, No. 95-754 (hereafter "petition"). In a response to that petition filed herewith, cross petitioners acknowledge a deepening split among the circuits on the important issues presented in the petition and agree that review should be granted. Moreover, for much the same reasons as those offered in the petition, this Court should also grant review of this cross-petition to consider the claims that the Eleventh Circuit held were preempted by federal law. By granting both the petition and the cross-petition, the Court will have the opportunity to resolve a broad spectrum of issues regarding medical device preemption that have divided the lower federal and state courts.

OPINIONS BELOW

The opinion of the court of appeals is reported at 56 F.3d 1335 (11th Cir. 1995), and is reproduced in the appendix to the petition ("Pet. App.") at 1a. The unreported opinion of the United States District Court for the Middle District of Florida is reproduced at Pet. App. 1b.

JURISDICTION

The judgment of the court of appeals was entered on July 3, 1995. Cross-respondent filed a timely petition for rehearing and suggestion for rehearing in banc on July 24, 1995, which the court of appeals denied on August 15, 1995 (Pet. App. 1e). The petition for writ of certiorari in No. 95-754 was filed on November 13, 1995, and placed on the docket on November 14, 1995. This cross-petition is being filed within 30 days thereafter. This Court has jurisdiction over the petition and this cross-petition under 28 U.S.C. § 1254(1) and Rule 12.5 of this Court.

STATUTES AND REGULATIONS INVOLVED

The principal statutes and regulations involved in this case are reproduced in the appendix to this cross-petition ("Cross-Pet. App.").

STATEMENT OF THE CASE

Approximately five years ago, a pacemaker lead manufactured by cross-respondent failed suddenly, causing injuries to cross-petitioner Lora Lohr and requiring her to undergo emergency surgery. Pet. App. 6a. Taken together, the petition and cross-petition present the question whether cross-petitioners will be able to seek recovery for their injuries under Florida common-law or whether, as cross-respondent maintains, a federal law enacted in 1976 to protect consumers from potentially dangerous medical devices was intended to bar their access to the tort system entirely. The structure of the federal medical device laws is described in Part A below. Part B briefly considers the facts and the proceedings in the district court, and Part C sets out the key holdings of the court of appeals.

A. The Basic Structure of the Medical Device Amendments.

Prior to 1976, medical devices were essentially unregulated. Although the Food and Drug Administration ("FDA") had some authority to seize adulterated and misbranded devices that were already on the market, it had no specific authority to prevent the entry of a medical device on the market, as it had for many years with respect to drugs. *See* H.R. Rep. No. 853, 94th Cong., 2d Sess. 8-10 (1976). In 1976, however, Congress enacted the Medical

Device Amendments ("MDA") to the Food, Drug and Cosmetic Act, which sought to impose a regulatory structure through which medical devices would enter the market. P.L. No. 94-295, 90 Stat. 539 (1976)(codified at 21 U.S.C. § 360c *et seq.*). The law was enacted largely in response to problem devices highlighted by the catastrophe surrounding the Dalkon Shield intrauterine device, whose marketing was essentially unregulated and whose faulty design had caused serious injuries to the reproductive systems of thousands of women. H.R. Rep. No. 853, *supra*, at 8, 12. Thus, the principal purpose of the MDA was to increase consumer protection by preventing the distribution of dangerous devices and ensuring that only safe and effective devices reached the market. *Id.*; S. Rep. No. 33, 94th Cong., 2d Sess. 1-2 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070-71. Congress placed responsibility for implementing and enforcing the MDA in the FDA.

Under the MDA, devices fall into three classes. Class I devices, such as tongue depressors, are those for which "general controls," such as record keeping and good manufacturing guidelines applicable to all devices, are sufficient to provide a reasonable assurance of safety and effectiveness. 21 U.S.C. § 360c(a)(1)(A).

Class II devices, such as certain types of hearing aids, 21 C.F.R. § 874.3300(b)(2), are those for which general controls alone are insufficient to protect public health. *See* 21 U.S.C. § 360c(a)(1)(B). Thus, Class II devices are subject, in the FDA's discretion, to "special controls," which may include performance standards, post-market surveillance, patient registries, and other measures deemed appropriate by the FDA. *See* 21 C.F.R. § 860.3(c)(2).

Finally, Class III devices are those for which the regulation provided for Class I and Class II devices is

insufficient, and the device either operates to sustain human life, is of substantial importance in preventing impairment of human health, or poses a potentially unreasonable risk to patients. 21 U.S.C. § 360c(a)(1)(C). In theory, Class III devices must undergo pre-market approval ("PMA"), a process which obligates the manufacturer to design and implement a clinical investigation, and submit the results of that investigation to the FDA. *See* 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20. The manufacturer's PMA application must contain proposed labeling for the device, a sample of the device, and other information. *See generally id.* Ultimately, the FDA may grant pre-market approval if it finds that there is "reasonable assurance" that the device is safe and effective. 21 U.S.C. § 360e(d)(2).

However, the PMA process does not apply to the vast majority of devices, because of two major exceptions. **First,** under the MDA, a device that is of the same model as a device marketed prior to the effective date of the 1976 Act—a so-called "grandfathered" device—is not subject to pre-market approval, even if it is a Class III type of device. *See, e.g.*, 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1). Such pre-MDA devices do not have to obtain pre-market approval until 30 months after the FDA classifies the device in Class III, or within 90 days after the FDA issues a regulation calling for PMA applications for that type of device under section 515(b) of the Act, 21 U.S.C. § 360e(b), *whichever is later. Id.* § 351(f)(2)(B). In other words, a "grandfathered" device may continue to be sold, without any pre-market approval, until it is both classified in Class III *and* 90 days have elapsed since the FDA has issued a section 515(b) regulation calling for a PMA application. The second condition has not yet occurred for the type of pacemaker

device at issue in this case. *See* 21 C.F.R. § 870.3610(c)("No effective date has been established of the requirement for premarket approval" for pacemakers).

Second, devices marketed *after* the MDA's 1976 effective date—such as the model of pacemaker implanted in Lora Lohr—may also bypass the PMA process, if their manufacturers can show that the device is "substantially equivalent" to either a "grandfathered" pre-MDA device, or a Class I or Class II device. 21 U.S.C. § 360c(f)(1)(A). This exception to pre-market approval, known as the "510(k)" process, simply requires the manufacturer to notify the FDA under section 510(k) of the Act of its intent to market the device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA "predicate device." 21 U.S.C. § 360(k); *see id.* § 360c(f)(1). There is no dispute that Ms. Lohr's pacemaker, like all but a tiny percentage of all devices, *see* petition at 6, reached the market through the 510(k) process. Pet. App. 6a.

Unlike the PMA process, a 510(k) pre-market notification is not intended to scrutinize devices for official FDA approval of safety and effectiveness. *Compare* 21 C.F.R. § 814.45(c)(PMA), *with id.* § 807.100(b)(510k). Because the FDA has never required a PMA for pacemaker devices, pacemakers introduced after the MDA's effective date reach the market solely on the basis of substantial equivalence. 21 C.F.R. § 870.3610(c). Indeed, a government report analyzing failures of Medtronic's pacemaker leads noted that

> [b]ecause each new lead was determined to be "substantially equivalent" to a previously marketed lead ... each one "piggybacked" on its

> predecessors through FDA's 510(k) review process. This process does not require FDA to determine that any of these models are safe and effective—and FDA has not done so.

U.S. General Accounting Office, *Medical Technology: For Some Cardiac Pacemaker Leads, the Public Health Risks Are Still High* 1 (GAO/PEMD-92-20 Sept. 1992). Among other reasons, manufacturers prefer the 510(k) process because it is far less costly than obtaining a PMA. Pet. App. 19a n.14.

B. Facts and District Court Proceedings.

In January 1987, Ms. Lohr, then 27 years old, was implanted with a Medtronic pacemaker and its related components. Thereafter, on December 30, 1990, Ms. Lohr's pacemaker failed, resulting in a "complete heart block," which required her to undergo emergency surgery and replacement of Medtronic's pacemaker. Complaint ¶ 7, Eleventh Circuit Record Excerpts ("R.E.") 8. Ms. Lohr's treating physicians attributed the pacemaker failure to a defect in Medtronic's pacemaker lead—a wire connected to the pacemaker that delivers the electrical impulse to the heart. Pet. App. 6a.

Cross-petitioners filed this case on March 9, 1993, in Florida state court, which cross-respondent removed to the United States District Court for the Middle District of Florida on the basis of diversity of citizenship. Pet. 6a. The complaint stated that Medtronic had designed, manufactured, and assembled its pacemaker in an unreasonably dangerous manner and that the pacemaker was prone to sudden, catastrophic failure. The complaint further alleged that cross-respondent had failed to warn Ms. Lohr or her

physicians of the tendency of the product to life-threatening failure, despite Medtronic's knowledge of other prior failures. As a result of the pacemaker failure, Ms. Lohr alleged pain, scarring, physical handicap, and mental suffering. Cross-petitioner Michael Lohr claimed loss of consortium based on Ms. Lohr's injuries. Complaint, ¶¶ 6-12, 15-16, R.E. 8-10.

Medtronic filed a motion for summary judgment arguing that cross-petitioners' tort claims were preempted by 21 U.S.C. § 360k(a), the part of the MDA which preempts state-law "requirements" that are "different from, or in addition to" certain federal requirements established under the MDA. Pet. App. 7a. The district court denied the motion on the ground that vindication of cross-petitioners' common-law claims would not stand as an obstacle to the objectives of the MDA. Pet. App. 5d. Later, however, the district court reversed itself and granted summary judgment to cross-respondent in light of the Eleventh Circuit's decision in *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994)(per curiam), an MDA preemption case which the district court interpreted as requiring preemption of all product liability claims concerning a medical device. Pet. App. 2b.

C. The Decision of the Court of Appeals.

The Eleventh Circuit reversed in part, and affirmed in part, holding that cross-petitioners' design-defect claims could go forward, but that 21 U.S.C. § 360k(a) preempted their claims based on a failure-to-warn or defects in the manufacturing of the pacemaker lead. For the most part, cross-petitioners concur in cross-respondent's description of the court of appeals' opinion contained in the petition in No.

95-754 (at 8-10), and thus we review here only the court's key holdings.

First, the court of appeals held that 21 U.S.C. § 360k(a) was intended to preempt at least some state-law damage actions. On this threshold question, the Eleventh Circuit believed that it was bound by its prior *per curiam* decision in *Duncan, supra*, but indicated that if it were writing "on a clean slate," a different result might be in order. Pet. App. 11a.

Second, despite the language of section 360k(a), which preempts only certain state and local requirements that are "different from, or in addition, to" requirements under the MDA, the court of appeals held that cross-petitioners' manufacturing-defect and failure-to-warn claims would be preempted even if they sought only to enforce federal standards in those areas. On this issue, the Eleventh Circuit believed that one of its prior preemption rulings under the federal pesticide statute was controlling. *See* Pet. App. 13a.

Third, the court of appeals held that the section 510(k) process, because it merely "grandfathers" onto the market devices that are similar to pre-MDA devices, does not itself establish preemptive "requirements," Pet. App. 26a-29a, and that there existed no other MDA requirements relating to device design applicable to the Medtronic pacemaker lead that could be said to preempt cross-petitioners' design-defect claims. Pet. App. 29a. This holding is the subject of the petition in No. 95-754.

Finally, the Eleventh Circuit held that the Lohrs' failure-to-warn and manufacturing-defect claims were preempted, not on the basis of specific MDA requirements relating to warnings for, or the manufacture of, pacemakers, but on the basis of the FDA's general good manufacturing practices and labelling regulations applicable to all types of

medical devices. Pet. App. 29a-32a. In so holding, the court of appeals rejected cross-petitioners' reliance on an FDA preemption regulation which, as a prerequisite to preemption of a state device requirement under section 360k(a), demands that there be a "specific counterpart [FDA] regulation[]" or "[an]other specific requirement applicable to a particular device under the act...." 21 C.F.R. § 808.1(d). The court acknowledged, however, that its holding was at odds with holdings of other courts, including that of the Ninth Circuit. Pet. App. 20a-21a.

REASONS FOR GRANTING THE WRIT

I. THE DECISION BELOW CONFLICTS WITH DECISIONS OF OTHER COURTS OF APPEALS AND BROADENS THE DISARRAY AMONG THE FEDERAL AND STATE COURTS ON AN IMPORTANT ISSUE OF FEDERAL LAW.

The court of appeals held that cross-petitioners' claim alleging a design defect in cross-respondent's pacemaker was not preempted by the MDA, but that her claims alleging defective manufacturing and failure to warn of the device's risks were preempted. These rulings conflict with decisions of other courts of appeals on three grounds.

First, the court of appeals held that an award of damages under state tort law may constitute a "requirement" and thus meets the threshold test for preemption under 21 U.S.C. § 360k(a). *See* Pet. App. 11a. This holding is in accord with decisions of other circuits,[1] but is in direct

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[1] *See, e.g., Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Stamps v. Collagen* (continued...)

conflict with a recent decision of the Ninth Circuit and decisions of other lower federal and state appellate courts.[2] The Eleventh Circuit concluded that its holding was required by its prior *per curiam* decision in *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994), a one-paragraph order preempting several damage claims concerning an experimental medical device. The court noted, however, that, if not for *Duncan*, the question whether MDA preemption reaches state-law damage actions "might present a difficult question...." Pet. App. 11a. This Court should grant review to consider this threshold issue—whether MDA preemption reaches state-law damage actions—which affects every MDA preemption case before the federal and state courts.

Second, conflicts have arisen on the question whether, and in what circumstances, claims regarding section 510(k) devices are subject to MDA preemption. This conflict in circuit authority is important because, as Medtronic's petition noted (at 6), showing "substantial equivalence" to a pre-MDA unregulated device is the pathway to the market for well over 90 percent of all medical devices. Thus, section 510(k) applies not only to all Class I and Class II devices, but to the great majority of Class III devices, the failure of which may lead to death or serious injury if they are not

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[1](...continued)
Corp., 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993).

[2] *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995); *Mulligan v. Pfizer*, 850 F. Supp. 633 (S.D. Ohio 1994); *Haudrich v. Howmedica, Inc.*, 642 N.E.2d 206, 204 Ill.Dec. 744 (Ill. App. 1994).

safe, as Ms. Lohr's experience with Medtronic's lead illustrates.

The Eleventh Circuit below, Pet. App. 26a-29a, as well as the Fifth Circuit in *Feldt v. Mentor Corp.*, 61 F.3d 431, 438 & nn.11-12 (1995), and the Hawaii Supreme Court in *Larsen v. Pacesetters Systems, Inc.*, 837 P.2d 1273, 1282 (Haw. 1992), have held that the section 510(k) "substantial equivalence" process does not itself establish preemptive requirements.[3] On this issue, the court below correctly noted that medical devices entering the market under section 510(k) do so not because the FDA has found them to be safe and effective, or because they have met any federal standards, but simply because they have been shown to be similar to devices that were already on the market prior to the MDA's passage in 1976, which were granted an exemption from any pre-market surveillance at that time. Pet. App. 26a-29a; *see Feldt*, 61 F.3d at 438 n.12 ("a new [510(k)] device may be as safe as a predicate device that itself is unreasonably dangerous"). Nevertheless, as Medtronic explained in its petition (at 11-12), these holdings are in direct conflict with decisions of the Third and Fourth Circuits.[4]

Moreover, as exemplified by the disposition of each of the causes of action in this case, the circuit split on section 510(k) devices is further complicated by various courts'

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[3] *See also, e.g., Oja v. Howmedica, Inc.*, 848 F. Supp. 905, 906-07 (D. Colo. 1994), *appeals pending*, Nos. 95-1085 *et al.* (10th Cir.); *Sylvester v. Mentor Corp.*, 1995 La.App. Lexis 2490, *17-*18 (La. App. Sept. 20, 1995).

[4] *English v. Mentor Corp.* 67 F.3d 477, 481-82 (3d Cir. 1995); *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392, 399-400 (4th Cir. 1995).

resolutions of particular types of product-liability claims. The court of appeals below held that design-defect claims are not preempted because no federal "requirements" are applicable to the design of pacemakers, as that term is used in 21 U.S.C. § 360k(a). Pet. App. 24a-29a. The Fifth Circuit in *Feldt*, 61 F.3d at 436-38, came to precisely the same result on the same grounds.[5] On the other hand, because of their view that the 510(k) process itself is preemptive, the Third and Fourth Circuits have taken the opposite approach, preempting design-defect claims regarding Class III medical devices.[6]

For their part, cross-petitioners challenge the court of appeals' holdings that their manufacturing-defect and failure-to-warn claims are preempted. Despite an FDA regulation under which only device-specific requirements may have preemptive effect, 21 C.F.R. § 808.1(d)(*reprinted in* Cross-Pet. App. 3a), the Eleventh Circuit held that the FDA's *generally applicable* good manufacturing practices and product labelling rules preempted those claims. Pet. App. 29a-36a. While these holdings are consistent with the First Circuit's decision in *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 18-19 (1st Cir. 1994), and the Fifth Circuit's decision in *Feldt*, 61 F.3d at 435-36, they are at odds with the previously discussed rulings by the Ninth Circuit and other state and federal courts that the MDA does not preempt damage actions at all, *see supra* note 2, and decisions holding that *general* FDA requirements cannot trigger

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[5] *See also, e.g., Dow v. Baxter Healthcare Corp.*, 899 F. Supp. 822, 1995 WL 566170, *1 (D. Mass. Sept. 21, 1995).

[6] *See English*, 67 F.3d at 481-82; *Duvall*, 65 F.3d at 399-400.

preemption of manufacturing-defect and other claims involving 510(k) devices.[7]

Third, the Eleventh Circuit ruled that cross-petitioners' manufacturing-defect and failure-to-warn claims were preempted, even if those claims did nothing more than seek to enforce federal standards regarding device labelling and good manufacturing practices applicable to devices generally. Pet. App. 13a-14a. Cross-petitioners maintain, for instance, that Medtronic's manufacturing practices did not comport with governing FDA standards, and, thus, that her claim was not "different from, or in addition to" any applicable federal requirement under 21 U.S.C. § 360k(a). *See also* 21 C.F.R. § 808.1(d)(2)("substantially identical" state or local requirements not preempted). Believing itself bound by its prior decision in *Papas v. Upjohn*, 985 F.2d 516, 518-19 (11th Cir.), *cert. denied*, 114 S. Ct. 300 (1993), a preemption ruling under the federal pesticide law, the court of appeals held that allowing such claims to go forward would impermissibly place the jury in the shoes of the regulatory agency. This ruling demeans the ability of jurors to apply the law and is, in cross-petitioners' view, at odds with section 360k(a)'s plain language, but it is in accord with the views of several other courts. *See, e.g., Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 29 (1st Cir. 1995). On the other

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[7] *Fender v. Medtronic, Inc.*, 887 F. Supp. 1326, 1331 (E.D. Cal. 1995)(no preemption of manufacturing-defect claim concerning same Class III pacemaker device at issue here); *Mulligan*, 850 F. Supp. at 635-36; *Oja*, 848 F. Supp. at 906-07; *Larsen*, 837 P.2d at 1282; *see also Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246 (5th Cir. 1989)(manufacturing-defect claim regarding Class II tampon not preempted because no specific FDA regulation on point).

hand, the Third, Seventh, and Eighth Circuits, have taken the opposite position, holding that there is no preemption under the MDA where the plaintiff's state-law claim would impose a duty that goes no further than an applicable federal regulatory standard.[8]

* * *

Because of these deepening and fundamental conflicts on the scope of MDA preemption, the fate of a personal-injury claim involving a medical device is now governed by geographical happenstance or whether, within a particular circuit, the suit is maintained in federal or state court. *Compare Mitchell*, 67 F.3d 1268 (Seventh Circuit decision preempting some damage claims), *with Haudrich*, 642 N.E.2d 206 (Illinois decision holding no preemption of damage claims under MDA). With the exception of the District of Columbia, Tenth, and Federal Circuits, all of the federal appeals courts have addressed MDA preemption, and several have done so more than once.[9] The issues have been thoroughly explored by the lower courts, and it is time for this Court to bring some order to the chaos that has been created by their conflicting decisions.

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[8] *Michael v. Shiley*, 46 F.3d 1316, 1328 (3d Cir.)(claim not preempted where "it is the FDA's own requirement that [plaintiff] would have the state enforce"), *cert. denied*, 116 S. Ct. 67 (1995); *Mitchell v. Collagen Corp.*, 67 F.3d 1268, 1995 U.S. App. Lexis 27709, *32 & n.9 (7th Cir. Oct. 2, 1995); *National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 993 (8th Cir. 1994); *accord Ministry of Health v. Shiley*, 858 F. Supp. 1426, 1439 (C.D. Cal. 1994); *Reiter v. Zimmer, Inc.*, 830 F. Supp. 199, 204 (S.D.N.Y. 1993).

[9] *See* petition at 11-16 & nn.11-12 (citing circuit court decisions).

Moreover, the question whether Congress intended to bar medical device consumers from obtaining compensation for their injuries under state tort law in an important one, as evidenced by the large number of reported decisions concerning a wide variety of medical devices, such as the pacemaker lead whose failure led to Lora Lohr's emergency surgery.[10] In sum, the Court should grant review to resolve this confusion and to provide guidance for both medical device consumers and manufacturers.

II. THE COURT OF APPEALS' PREEMPTION OF TWO OF CROSS-PETITIONERS' COMMON-LAW CLAIMS IS AT ODDS WITH CONGRESSIONAL INTENT.

The need for review of the issues presented here and in Medtronic's petition is made more compelling by the erroneous conclusion reached by many courts that MDA preemption extends to state-law damage awards. Perhaps recognizing that section 360k(a) does not contain the "clear and manifest" congressional intent necessary to preempt state law, *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 605, 611 (1991), the court of appeals stated that were it "writing on a clean slate," Pet. App. 11a, it might have concluded that section 360k(a) does not reach state tort law at all. Pet. App. 11a. As we now show, the language and history of section 360k(a), and the FDA's regulations promulgated thereunder, indicate that the court of appeals'

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[10] *See also, e.g.*, *Michael*, 46 F.3d at 1321 (defective artificial heart valve that caused hundreds of deaths); *Talbott*, 63 F.3d at 26 (death caused by heart catheter failure); *Mendes*, 18 F.3d at 15 (failed pacemaker); *Moore*, 867 F.2d at 243 (toxic shock syndrome attributed to defects in manufacture and design of tampon).

doubts were well founded, thus providing a further basis for review.

A. Cases holding that the MDA preempts state-law damage claims have misinterpreted section § 360k(a). That section does not extend to all "state law," which is language that this Court in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 522 (1992), considered important in holding that some common-law "requirements" could be preempted by the Public Health Cigarette Smoking Act of 1969. Rather, section 360k(a) states only that "[n]o State or political subdivision of a State may establish or continue in effect" certain device "requirements." To equate a jury award or a court adjudication of a common-law claim with a "State . . . establish[ing] or continu[ing] in effect" a device "requirement" strains ordinary English usage beyond the breaking point. *See Haudrich*, 642 N.E.2d at 210.[11]

The courts finding preemption have focussed narrowly on the fact that section 360k(a) uses the word "requirement" because that word also appeared in the statute at issue in *Cipollone*. *See, e.g., Stamps*, 984 F.2d at 1421; Pet. App. 11a. But whether the word "requirement" covers damage actions depends on its context in the statute at issue. *See Brown v. Gardner*, 115 S. Ct. 552, 555 (1994).

Section 360k(a) uses "requirement" three times:

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[11] *See also Kennedy*, 67 F.3d 1453; Gail Javitt, *I've Got You Under My Skin And I Can't Get Redress: An Analysis of Recent Case Law Addressing Preemption of Manufacturer Liability for Class III Medical Devices*, 49 Food & Drug Cosm. L.J. 553, 559 (1994)(cases preempting damage claims "appear to ignore both the explicit language of the MDA and the clear legislative history leading up to that Act"). *But see, e.g., Stamps*, 984 F.2d 1416; *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992).

> [N]o state . . . may establish or continue in effect with respect to a device intended for human use any *requirement* (1) which is different from, or in addition to, any *requirement* applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a *requirement* applicable to a device under this chapter (emphasis added).

The latter two uses of "requirement" in section 360k(a) are unambiguous references to the statutory and regulatory requirements imposed by the MDA and FDA regulations, not references to damage remedies or to the common law. *See Haudrich*, 642 N.E.2d at 209-10; Adler & Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 926 (1995). The first use of "requirement" in § 360k(a), referring to actions of states and their political subdivisions that may be preempted by the MDA, appears to have the same meaning as the latter two uses, as it also makes no reference to damages actions or the common law. But the Eleventh Circuit's holding that state-law damage awards may be preempted would mean that Congress intended the term "requirement" to be interpreted in two different ways within a single sentence and, thus, runs headlong into "the basic canon of statutory construction ... that identical terms within an Act bear the same meaning." *Reno v. Koray*, 115 S. Ct. 2021, 2026 (1995)(internal quotation and citation omitted). *See also* H.R. Rep. No. 853, *supra*, at 4, 45-46 (MDA's legislative history, making no mention of intent to preempt state common-law claims, and referring solely to potential for preemption of state and local statutes and regulations addressed specifically to medical devices).

B. The MDA contains another provision that, consistent with the presumption against preemption, reveals Congress' assumption that state-law damage actions will co-exist with federal regulation of medical devices. Under 21 U.S.C. §§ 360h(a), (b), and (c), the FDA has the power to notify the public and health professionals of unreasonable risks associated with devices and to order device manufacturers to repair, replace, or provide refunds and reimbursements with respect to such devices. Subsection (d) of section 360h, however, entitled "Effect on Other Liability," provides:

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

This provision is "[o]f vast significance" to the preemption analysis because it "specifically contemplates [actions under] state law [for] liability and damages" against manufacturers of medical devices, and "unambiguously prohibits a finding of liability pursuant to section [360h](b) and (c) from shielding a defendant from state liability and damages...." *Mulligan*, 850 F. Supp. at 636. In short, section 360h(d), taken together with other indicia of congressional intent, demonstrates Congress' understanding

that common-law liability would complement, rather than be supplanted by, regulation under the MDA.[12]

C. Finally, the FDA—the agency charged by Congress with interpreting the MDA and implementing its preemption provision—has reasonably construed the MDA not to preempt remedies, such as common-law damage actions, based on *general* legal duties. Under the FDA's regulations, 21 U.S.C. § 360k(a) "does not preempt State or local requirements of *general applicability* where the purpose of the requirement relates ... to other products in addition to devices ...." 21 C.F.R. § 808.1(d)(1) (emphasis added). The court of appeals purported to consider the FDA's views, which it agreed were entitled to deference. Pet. App. 17a; *see Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 714 (1985). However, the court did not even discuss this regulatory language which would, by its terms, save from preemption cross-petitioners' claims based on the general duties under Florida law to warn about a product's dangers and to manufacture a product without defect. *Accord Kennedy*, 67 F.3d 1453 (Reinhardt, J., concurring).[13]

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[12] While the Eleventh Circuit recognized that section 360h(d) was a "savings clause" for damage actions, it claimed, without pointing to any statutory language or history, that section 360h(d) preserved only non-tort liability. Pet. App. 12a. *But see* H.R. Rep. No. 853, *supra*, at 21-23 (making no mention of limitation on section 360h(d) to non-tort remedies).

[13] The FDA's views on this subject have extended to other regulatory pronouncements in which the agency has stated that state-law judicial remedies, such as product liability claims, are not preempted by 21 U.S.C. § 360k(a). *See* Advisory Opinion of

(continued...)

In addition, the FDA's preemption regulations provide that:

> [s]tate or local requirements are preempted only where the Food and Drug Administration has established *specific counterpart requirements applicable to a particular device* under the act, thereby making any existing state or local requirement different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d)(emphasis added). This language strongly indicates that FDA rules applicable generally to devices—such as the good manufacturing practices and labelling rules—would not have preemptive effect. *See, e.g., Kennedy*, 67 F.3d 1453. The court of appeals, however, held otherwise, stating that FDA regulations need not be "device-specific" to preempt state-law tort claims. Pet. App. 20a. The court recognized that its view was in conflict with the Ninth Circuit, the Hawaii Supreme Court, and several district court decisions, *see* Pet. App. 20a-21a & n.15, all of which require "device-specific" regulations before

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[13](...continued)
FDA's Associate Commissioner for Regulatory Affairs, dated Mar. 8, 1984 (Cross-Pet. App. 4a-6a); Letter from Chief of FDA's Regulatory Staff, dated Feb. 2, 1987 ("FDA believes that section 521 [§ 360k(a)] does not preempt general product liability requirements")(Cross-Pet. App. 7a).

preemption can occur and provide yet another reason for this Court to grant review.[14]

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[14] Consistent with the FDA's regulatory stance, the Justice Department has filed an amicus brief on behalf of the FDA which maintains that pre-market approval requirements are not "specific requirements" with respect to a device and, therefore, do not preempt state-law damage claims, explicitly noting its disagreement with *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993). *See* Brief for United States as Amicus Curiae in *Talbott v. C.R. Bard*, No. 94-1951 (1st Cir.), at 14 n.5, 25-26 n.7. An example of device-specific regulations are those pertaining to warning labels for tampons. 21 C.F.R. § 801.430; *see Moore*, 867 F.2d at 246 (duty-to-warn claim concerning tampon preempted in light of specific federal warning for tampons, but manufacturing-defect and design-defect claims not preempted).

CONCLUSION

The cross-petition for a writ of certiorari should be granted.

Respectfully submitted,

ROBERT L. COWLES
DANIEL C. SHAUGNESSY
COWLES & SHAUGNESSY, P.A.
Suite 901
233 East Bay Street
Jacksonville, FL 32202
(904) 359-9500

ROBERT F. SPOHRER
SPOHRER, WILNER & MAXWELL, P.A.
444 East Duval Street
Jacksonville, FL 32202
(904) 354-8310

BRIAN WOLFMAN
(Counsel of Record)
ALLISON M. ZIEVE
ALAN B. MORRISON
PUBLIC CITIZEN LITIGATION GROUP
1600 20th Street, N.W.
Washington, D.C. 20036
(202) 588-1000

Attorneys for Cross-Petitioners

December 6, 1995

PRINCIPAL STATUTORY PROVISIONS INVOLVED

21 U.S.C. § 360k provides:

> **State and local requirements respecting devices**
>
> **(a) General rule**
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.
>
> **(b) Exempt requirements**
>
> Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

* * *

21 U.S.C. § 360h(d) provides:

Effect on Other Liability

Compliance with an order [requiring a manufacturer to repair, replace, or provide reimbursement for expenses relating to an unsafe device] issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

PRINCIPAL REGULATORY PROVISION INVOLVED

21 C.F.R. § 808.1(d) provides in part:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act [21 U.S.C. § 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices. ...

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food & Drug Administration
Rockville, MD 20857

MAR -8 1984

National Women's Health Network
c/o Robert E. Manchester, Esq.
Manchester & O'Neill, P.C.
Attorneys at Law
P.O. Box 1459
Burlington, Vermont 05402-1459

Re: Docket No. 83A-0140/AP

Dear Mr. Manchester:

This letter is in response to your letter of April 25, 1983, submitted on behalf of your client, the National Women's Health Network (the network). You requested an advisory opinion under 21 CFR 808.5, 10.85, 10.20, and 10.30(c)(1), declaring that section 521 of the Federal Food, Drug, and Cosmetic Act (the act)(21 U.S.C. 360k) does not preempt the application of State law injunctive remedies to intrauterine contraceptive devices (IUDs) produced, marketed, and inserted into women prior to the enactment of the Medical Device Amendments of 1976 (Pub. L. 94-295) and still being worn by women in the United States and other countries.

Section 521(a) of the act contains special provisions governing the regualtion of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect with respect to a medical device intended for human use any requirement having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different

from, or in addition to, any requirement applicable to such device under any rpovision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to a device under the act. Under section 521(a) of the act, the act preempts only State or local requirements that directly and specifically relate to devices. For a State provision to be a requirement with respect to a device within the meaning of Section 521 of the act, and thereby a candidate for preemption, it is necessary that the State provision relate to the device itself. There is no indication in the legislative history of section 521(a) that Congress intended that the section preempt State or local requirements respecting general enforcement, including available legal remedies, or State or local statutes that only incidentally apply to devices. Rules or requirements established by States to govern legal remedies available under the State judicial system are not "requirements with respect to a device" within the meaning of section 521(a) of the act.

FDA also advises that section 521(a) of the act preempts State or local requirements applicable to adevice only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device or class of devices under the act; it is necessary that an FDA requirement exist before a State requirement is preempted. There is no FDA counterpart (regulations or specific requirements applicable to IUDs) to the State provisions the network has invoked in National Women's Health Network, et. al. v. A.H. Robins Company, Inc., No. 81-0004-N (D. Mass. filed January 2, 1981). Thus, those State provisions are not preempted under section 521(a) of the act.

In conclusion, FDA believes that section 521(a) of the act does not preempt the application to IUDs of State law injuctive remedies. This advisory opinion does not address

the merits of the application of such remedies in any action filed by the network in the State of Massachussets or any other State.

Sincerely yours,
s/
Joseph P. Hile
Associate Commissioner
for Regulatory Affairs

cc: [omitted]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food & Drug Administration
Rockville, MD 20857

FEB 02 1987

Cindy Whaley, Esquire
Winston, Cashatt
Attorneys at Law
Seattle First Financial Building
Spokane, WA 99201

Dear Ms. Whaley:

Enclosed is the information that you requested in our phone conversation of January 27, 1987 regarding preemption and medical devices. As you can see from these FEDERAL REGISTER documents, it is the Food and Drug Administration's (FDA) position that section 521 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(k)) preempts only state and local requirements that are specifically related to medical devices. Therefore, FDA believes that section 521 does not preempt general product liability requirements.

If I can be of any further assistance to you, please let me know.

Sincerely yours,
s/
Joseph M. Sheehan
Chief, Regulations Staff

Enclosures